REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 1-45 are pending in the application. The Examiner has designated Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 as drawn to the elected species and Claims 11-12, 14-15, 22-24, 34, 40, and 44-45 as withdrawn. Consistent with 37 C.F.R. §1.141, Applicant respectfully requests recombination of all of Claims 1-45 if, as argued below, the generic claims are found to be allowable.

Section 103 Obviousness Rejections

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,238,888 to Gentz et al. in view of U.S. Pat. No. 6,046,160 to Obi-Tabot and U.S. App. Publ. No. 2002/0146439 to DeLong et al. The Examiner relies upon the Gentz reference as teaching a composition for stimulating hair follicle production comprising collagen, dextran, glutamic acid, cysteine, and EDTA. The Examiner relies upon Obi-Tabot as teaching the use of denatured collagen in a skin treatment and DeLong as teaching a composition for hair growth in liquid form, which is solid at room temperature. Applicant respectfully traverses this rejection.

As noted previously, the Gentz reference is directed to various formulations designed to deliver keratinocyte growth factor-2 (KGF-2). The reference discloses, for example, liquid formulations, thickened and gel formulations, and lyophilized formulations. The sections relied upon by the Examiner as relevant to the use of dextran and gelatin are within the portion of Gentz discussing thickened and gel formulations. The Gentz patent merely lists gelatin and dextran in a long laundry list of gelling agents and there is no suggestion to combine those two components in the same formulation. Applicants note that the Gentz patent does not provide any exemplary gel formulations that include either ingredient, much less the two together. The Examiner has failed to explain why one of ordinary skill in the art would find Gentz suggestive

of using a formulation including both gelatin and dextran. There is simply no suggestion in the cited reference to combine these two ingredients. The Examiner appears to argue that one would have been motivated to replace the collagen of Gentz with denatured collagen due to the teachings of Obi-Tabot, but even if this were true, it does not answer the question of where one would find motivation to combine both gelatin (e.g., denatured collagen) and dextran.

If the Examiner is arguing that Obi-Tabot suggests adding denatured collagen to the composition of Gentz, Applicant respectfully disagrees. Obi-Tabot adds nothing to the Gentz disclosure. As discussed above, Gentz already suggests the use of gelatin, which is known in the art to be formed by heat-treating mature collagen, as a gelling agent. Thus, the sections of Obi-Tabot relied upon by the Examiner add nothing substantive to the Gentz disclosure. Importantly, the combination of Gentz and Obi-Tabot still fail to suggest a composition comprising both gelatin and dextran.

Further, the Gentz reference requires that the gelling agents used in the gel formulations taught therein produce a formulation that remains liquid at room temperature and solidifies when applied to the surface of the skin (at about 37°C) (see column 8, lines 53-59). Although the Gentz reference suggests dextran and gelatin as possible gel forming high molecular weight compounds, it only suggests the use of such compounds in gel compositions that exhibit reverse thermal gelation behavior as described above. Thus, the Gentz reference clearly only teaches gel formulations wherein the gel increases in viscosity with increases in temperature (see column 9, lines 52-60). The independent claims of the present application recite that the hydrogel matrix of the invention is administered in liquid form and is solid at temperatures below 33°C. This is directly contrary to the teachings of the Gentz reference, which requires thermoreversible gelation behavior wherein the gelling agents provide a formulation that is liquid at room temperature, but solidifies at physiologic temperature.

The Examiner attempts to rectify the deficiencies of Gentz with DeLong. The Examiner opines that because DeLong allegedly teaches the use of a liquid hair treatment composition that is solid at room temperature, one of ordinary skill in the art would be motivated to modify the express teachings of Gentz by ignoring the clear suggestion in Gentz to use reverse thermal gelation gels. This conclusion is simply unsupported by the art of record.

The DeLong reference merely describes the use of prostaglandin-containing compositions for treating hair loss. The Examiner relies upon two unrelated sections of the reference to conclude that DeLong suggests a composition that is liquid at treatment temperature and solid at room temperature. While para. 206 cited by the Examiner is directed to an exemplary liquid composition, para. 167 is completely unrelated to para. 206. Para. 167 merely describes a wax ingredient that can have a melting point within a wide range above room temperature. The Examiner is apparently suggesting that one would read this section as meaning that the compositions of DeLong are solid at room temperature. This is simply untrue. Applicant notes that the composition described in para. 206 does not contain a wax so there is no reason to suspect that the composition of Example 6 is solid at room temperature. Further, there is no reason to suspect that any composition taught in DeLong is solid at room temperature and liquid at treatment temperature. The mere fact that the references suggests that a wax ingredient can be added to a composition is insufficient to conclude that the final composition will be solid at room temperature. The concentration of the wax and the type of other ingredients would also factor into the characteristics of the composition. We also note that the wax discussed in para. 167 is described as an ingredient in a mascara useful to darken or thicken hair (see para. 164). As a result, this portion of the reference has no relevance to Gentz, which is obviously not directed to mascara compositions.

Even if the portions of DeLong relied upon by the Examiner actually suggested a composition that is solid at room temperature, which is obviously untrue, there would be no motivation to modify Gentz in the manner contemplated by the Examiner. As described above, Gentz teaches away from the invention by suggesting gel formulations that thicken as temperature increases, i.e., a reverse thermal behavior gel. The Examiner has not explained why one of ordinary skill in the art would be motivated to ignore this unambiguous teaching in Gentz. The Examiner simply notes that "it is known in the art that matrixes for hair growth can be administered in different liquid/solid states, depending on the desired effect." However, the Examiner has not supported this broad statement with any evidence other than DeLong, which is not relevant to the present invention as noted above. Further, even if this statement is true, it does not explain why one of ordinary skill in the art would be motivated to ignore the clear

teachings of Gentz to use gel formulations that thicken as its temperature increases to body temperature.

In sum, Applicant respectfully submits that the cited combination of references clearly fails to teach or suggest the present invention and requests reconsideration and withdrawal of this rejection.

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gentz et al., Obi-Tabot, and DeLong et al. as described above, and further in view of U.S. Pat. No. 6,372,494 to Naughton et al. The Examiner relies upon the Naughton reference as teaching injection of a hair growth composition and the remaining references as noted above. Applicant respectfully traverses this rejection.

The deficiencies of the combination of Gentz, Obi-Tabot and DeLong are discussed above and apply with equal force to this rejection. Applicants further respectfully disagree that one of ordinary skill in the art would be motivated to inject the gel composition of Gentz due to the teachings of Naughton. The Naughton reference only suggests injection of an aqueous suspension. The Examiner is relying on sections of Gentz directed to gel formulations, not aqueous suspensions. Naughton is silent as to injection of a gel formulation of the type described in Gentz.

As noted previously, the Gentz reference does not fairly teach or suggest the combination of gelatin and dextran, and only describes gel formulations that exhibit thermoreversible gelation characteristics, meaning the formulation remains liquid at room temperature and solidifies when applied to the surface of skin (i.e., solidifies at body temperature). Although the Gentz reference discloses dextran and gelatin in a long laundry list of gel forming high molecular weight compounds, there is no suggestion in the Gentz reference to combine the two components and certainly no suggestion to form a hydrogel matrix that is intended to be administered in liquid form, but which is solid at lower storage temperatures, such as below about 33°C. Instead, the Gentz reference very clearly teaches away from such a composition by suggesting that the gel formulations described therein exhibit thermoreversible gelation behavior where viscosity increases as temperature increases. This is directly contrary to Applicant's claimed invention and, as noted above, the remaining references of record cannot be viewed as correcting the clear

deficiencies of Gentz. As a result, Applicant respectfully requests reconsideration and withdrawal of this rejection.

It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office Fax No. (703) 872-9306 on the date shown below.

Tracey S. Wright — 12/10/04 Date